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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,645	04/05/2001	Yao Xiong Hu	146-1-002	5717

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EXAMINER
SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
1648	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/828,645	Applicant(s) Yao Xiong Hu
	Examiner A. R. SALMI	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 18, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *7-14 and 17-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *7-14 and 17-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment A, paper No.12, filed 7/18/2003. Claims 1-6, 15, and 16 have been canceled. Claims 19-22 have been added. Claims 7-14, 17-22 are pending before the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Please note any grounds of rejection that has not been repeated is removed.

Specification

The amendment filed on 7/18/2003 is objected to under 35 U.S.C. 132 because it introduces **new matter** into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the limitations of "oncoprotein epitope" in line 3 of newly amended claim 14 is new. The specification provides no support for said limitation Applicant is requested to point to specific page and line where the limitation maybe found.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of "oncoprotein epitope" in line 3 of newly amended claim 14 is new.

Claim Rejections - 35 USC § 112

Claims 7-14, 17-22 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 4/12/2003. Applicant argues that the peptides that are reactive with antibodies are defined in the specification as "antigenic." Applicants assert that the claim 7 is directed specifically to antibodies from peptides derived from the E2 early coding regions of human papillomavirus strains 16 and 18 and therefore is complete. Applicant's argument as part of amendment A, Paper NO. 12, filed 7/18/2003 has been considered fully, but they are not persuasive. At the onset Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The intended metes and bounds of polypeptides of the "E2" region is not defined. In addition, the invention is directed to or should be directed to detecting presence of serum antibodies only. Applicant's assertion that "claim 7 is directed specifically to antibodies from peptides derived from the E2 early coding regions of human papillomavirus strains 16 and 18 and therefore is complete" in Remarks, page 6, 1st full paragraph, does not make sense. This invention is a simple ELISA method for detecting serum antibodies against human papillomavirus E2 polypeptide, and nothing more. In order to conduct a diagnostic the peptide that is suppose to bind to the serum

antibody should be clearly and distinctly defined. E2 protein of papillomavirus is a large polypeptide and the specification does not define the intended E2 polypeptide. The rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 7, 14, 17-21 are rejected under 35 U.S.C. 102(b) as anticipated by Schoolnik et al (US Patent No.4,777,239) for reasons of record advanced in the previous Office Action mailed 4/12/2003. Applicant argues the rejection is improper because the Schoolnik et al does not disclose a peptide sequence which overlaps any of amino acids specified in SEQ ID NO: 1. Applicant admits on the record that Schoolnik et al teaches a series of seventeen synthetic peptides as useful in diagnosis and therapy of human papillomavirus (HPV) infection, further teaches the use of the peptides to detect the presence of antibodies against HPV. Applicant's argument as part of amendment A, Paper NO. 12, filed 7/18/2003 has been considered fully, but they are not persuasive. Applicant is reminded to carefully read the main claim 7, since no limitation of SEQ ID NO: 1 is present in claim 7 or other rejected claims dependent upon claim 7. Claim 8 and its dependent claims were not included in the rejection since Schoolnik et al do not anticipate the SEQ ID NO: 1. However, as Applicant has observed and admits on the record Schoolnik et al teaching and claims do indeed anticipate the broad limitations of the current claims. They teach E2 of human papillomavirus that can be utilized in detection of serum antibodies. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 102

Claims 7-14, 17-22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dillner et al (WO 91/18294)for reasons of record advanced in the previous Office Action mailed 4/12/2003. Applicant argues unlike Dillner et al the claimed invention is directed to detection of infection and/ or cellular abnormalities such as koilcytosis, hyperkerotosis, etc.... Applicant refers to recitations of the specification as providing teaching of at least five additional HPV strain that were not previously taught in Dillner et al. In addition, Applicants argues that the invention is not obvious over teaching of Dillner et al, because Dillner et al specifically teaches that it is not obvious that there would be homology between immunoreactive regions in HPV strains. Applicant's argument as part of amendment A, Paper NO. 12, filed 7/18/2003 has been considered fully, but they are not persuasive. First, Applicant's understanding of his/her own claimed invention is misplaced. Applicant dismisses the limitations of the broad claims, this is not permitted. Applicant is reminded that the teaching of detection method of Dillner et al indeed reads on the E2 protein that is present in claim 7, epitopes, etc.. This invention is not a method of detecting cancerous tissue under microscope i.e histological observation or hybridization assay of detecting oncogenes. This is simple detection of serum antibodies utilizing E2 polypeptide. The same polypeptide that is taught by Dillner et al. Why doesn't for instance five or eight amino acids long polypeptide from the middle of Dillner's polypeptide as taught on page 38 consider to overlap with the limitations of either claims 7, 8, or 10? If Applicant doesn't appreciate the scope of the claimed invention, Office certainly does

(emphasis added). In addition, applicant's assertion that Dillner did not teach that there would be homology between immunoreactive regions in HPV strains is an unsupported assertion. Moreover, it is irrelevant to the presently claimed invention whether or not homology is present or not. The fact is the E2 protein disclosed by Dillner anticipates Applicant's claim (emphasis added), if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Still further, Applicant has not taught new strains of HPV anywhere, has not detected or diagnosed any oncoprotein or koilcytosis, hyperkerotosis, simply reciting names in the specification is not teaching. Applicant has simply taken a well known product and utilized it in a well known method that is already taught in the art, Applicant admits on the record that Dillners' teaching is directed to detection of HPV utilizing E2 protein. That is the same as broad claims of the Applicant's own invention. The SEQ ID NO: 1 is only different by one amino acids, which would have been obvious to delete absent any unexpected result. The peptide disclosed by Dillner et al comprises the same epitopes as now claimed by the Applicant. There is nothing in the specification that indicates Applicant has observed any unexpected result in view of the above cited art. Applicant is requested to point to unexpected result (emphasis added), if any, in view of the Dillner et al reference. The rejection is maintained.

NEW GROUNDS OF REJECTION:

Claim Rejections - 35 USC § 112

Claims 7-14, 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite for recitation of "detect cervical cellular abnormalities", how does results of antigen antibody complex is interpreted to be detecting cellular abnormalities? Is this a histological method or ELISA method? The claim has been interpreted in light of the specification. However, since the specification is deficient in providing adequate teaching, the claim is considered vague and indefinite. This affects the dependant claims.

Claim 10 is indefinite, the intended epitopes are not defined.

Claim 20 is confusing for recitation of "cervical cellular abnormalities", how does antigen antibody complex is interpreted to detect cellular abnormalities.

Claim 21 is confusing for recitation of "cervical cellular abnormalities", how does antigen antibody complex is interpreted to detect cellular abnormalities such as koilcytosis, invasive cancer? The claim has been interpreted in light of the specification. However, since the

specification is deficient in providing adequate teaching, the claim is considered vague and indefinite.

Claim Objections

Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 20 incorporates many more papillomavirus types than is present in claim 7.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

8/4/2003

ALI R. SALIMI
PRIMARY EXAMINER